

NIGHTTIME SLEEP AID BERRY FLAVOR- diphenhydramine hydrochloride liquid WINCO FOODS, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

WINCO® Nighttime Sleep-Aid

Drug Facts

Active ingredient (in each 30 mL dose cup)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- avoid alcoholic beverages

Stop use and ask a doctor if sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning:

In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions

- take only one dose per day (24 hours)
- only use cup provided.

adults & children 12yrs & over	30 mL at bed time if needed or as directed by a doctor
Children under 12 yrs	do not use

Other information

- **each 30 mL dose contains:** potassium 5 mg, sodium 10 mg
- store at room temperature

Inactive ingredients

anhydrous citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, glycerin, potassium citrate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum.

PRINCIPAL DISPLAY PANEL

NDC 67091-630-06

Compare to the active ingredient in ZzzQuil™ Nighttime Sleep-Aid*

Nighttime Sleep-Aid

Diphenhydramine HCl

Non-Habit Forming

Makes you fall asleep fast

BERRY FLAVOR

Naturally and Artificially Flavored

No added alcohol

Not for Pain. Not for Colds.

Just for Sleep

6 FL OZ (177 mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SHRINK BAND IS MISSING OR

BROKEN

*This product is not manufactured or distributed by Procter & Gamble, the distributor of ZzzQuil™ Nighttime Sleep-Aid.



NIGHTTIME SLEEP AID BERRY FLAVOR

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-630
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	BERRY (Naturally and Artificially)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-630-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/09/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/09/2023	

Labeler - WINCO FOODS, LLC (056098817)

Revised: 4/2023

WINCO FOODS, LLC